

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA**

UNITED FOOD AND COMMERCIAL
WORKERS UNION, LOCAL No. 663, *et al.*,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF
AGRICULTURE,

Defendant.

Civil Action No. 0:19-cv-02660
The Honorable Joan N. Ericksen
Magistrate Judge Tony N. Leung

**MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANT'S MOTION TO DISMISS**

TABLE OF CONTENTS

INTRODUCTION	1
BACKGROUND	3
I. Statutory Background.....	3
II. Regulatory Background.....	4
A. The Traditional Inspection System.....	4
B. A New Approach to Swine Slaughter Inspection Regulation	6
C. Modernization of Swine Slaughter Inspection: The Proposed Rule	9
D. Modernization of Swine Slaughter Inspection: The Final Rule	11
III. Procedural Background	13
ARGUMENT	15
I. Plaintiffs Lack Standing to Bring this Action.	15
A. Standards of Review.....	15
B. Plaintiffs' Alleged Injuries Are Remote and Speculative.....	16
C. Plaintiffs' Alleged Injuries Are Not Fairly Traceable to the Government's Actions.	22
II. Plaintiffs Fail to State a Claim Upon Which Relief Can Be Granted.	25
A. Standards of Review.....	25
B. Plaintiffs' Alleged Injuries Fall Outside the FMIA's Zone of Interests.....	27
C. As a Matter of Law, USDA Does Not Have the Statutory Mandate to Regulate Worker Safety under the FMIA.	28
D. As a Matter of Law, NSIS Complies with the FMIA's Requirement that FSIS Inspectors Inspect Each Carcass and Part.	31
CONCLUSION	35

TABLE OF AUTHORITIES**CASES**

<i>Altera Corp. & Subsidiaries v. Comm'r,</i> 926 F.3d 1061 (9th Cir. 2019).....	29
<i>Am. Fed'n of Gov't Emps., AFL-CIO v. Glickman,</i> 215 F.3d 7 (D.C. Cir. 2000) (<i>AFGE I</i>).....	<i>passim</i>
<i>Am. Fed'n of Gov't Emps., AFL-CIO v. Veneman,</i> 284 F.3d 125 (D.C. Cir. 2002) (<i>AFGE II</i>)	<i>passim</i>
<i>Am. Fed'n of Gov't Emps., AFL-CIO v. Vilsack,</i> 672 F. App'x 36 (D.C. Cir. 2016).....	17
<i>Am. Mining Congress v. EPA,</i> 965 F.2d 759 (9th Cir. 1992).....	29
<i>Ashcroft v. Iqbal,</i> 556 U.S. 662 (2009).....	26
<i>Binno v. Am. Bar Ass'n,</i> 826 F.3d 338 (6th Cir. 2016).....	24
<i>Bowen v. Georgetown Univ. Hosp.,</i> 488 U.S. 204 (1988).....	28
<i>Cent. S.D. Co-op. Grazing Dist. v. Sec'y of USDA,</i> 266 F.3d 889 (8th Cir. 2001).....	26, 28, 29
<i>Chevron, U.S.A., Inc. v. Natural Resources Def. Council, Inc.,</i> 467 U.S. 837 (1984).....	31, 32
<i>City of Clarkson Valley v. Mineta,</i> 495 F.3d 567 (8th Cir. 2007).....	15
<i>Clapper v. Amnesty Int'l USA,</i> 568 U.S. 398 (2013).....	16, 17, 19
<i>Dawkins ex rel. Estate of Dawkins v. United States,</i> 226 F. Supp. 2d 750 (M.D.N.C. 2002)	22, 29

<i>Deerbrook Pavilion, LLC v. Shalala,</i> 235 F.3d 1100 (8th Cir. 2000).....	16
<i>Food & Water Watch, Inc. v. Vilsack,</i> 808 F.3d 905 (D.C. Cir. 2015)	17, 21, 22, 25
<i>Friends of Boundary Waters Wilderness v. Bosworth,</i> 437 F.3d 815 (8th Cir. 2006).....	32, 35
<i>Friends of Earth, Inc. v. Laidlaw Envt'l Servs., Inc.,</i> 528 U.S. 167 (2000).....	16
<i>Grocery Mfrs. Ass'n v. EPA,</i> 693 F.3d 169 (D.C. Cir. 2012)	24
<i>Home Box Office, Inc. v. FCC,</i> 569 F.2d 9 (D.C. Cir. 1977).....	29
<i>Iowa League of Cities v. EPA,</i> 711 F.3d 844 (8th Cir. 2013).....	16, 28
<i>Kenney v. Glickman,</i> 96 F.3d 1118 (8th Cir. 1996).....	29
<i>Lane v. Holder,</i> 703 F.3d 668 (4th Cir. 2012).....	24
<i>Lexmark Int'l, Inc. v. Static Control Components, Inc.,</i> 572 U.S. 118 (2014).....	26
<i>Lujan v. Defs. of Wildlife,</i> 504 U.S. 555 (1992).....	<i>passim</i>
<i>Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak,</i> 567 U.S. 209 (2012).....	26, 27
<i>McChesney v. FEC,</i> 900 F.3d 578 (8th Cir. 2018)	26
<i>Monsanto Co. v. Geertson Seed Farms,</i> 561 U.S. 139 (2010).....	16
<i>Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.,</i> 463 U.S. 29 (1983)	26

<i>Nat'l Meat Ass'n v. Harris,</i> 565 U.S. 452 (2012).....	4, 29
<i>Osborn v. United States,</i> 918 F.2d 724 (8th Cir. 1990).....	16
<i>Owner-Operator Indep. Drivers Ass'n v. U.S. Dep't of Transp.,</i> 831 F.3d 961 (8th Cir. 2016).....	18
<i>Pub. Citizen, Inc. v. FAA,</i> 988 F.2d 186 (D.C. Cir. 1993)	29
<i>Rohr v. Reliance Bank,</i> 826 F.3d 1046 (8th Cir. 2016).....	31
<i>Rosebud Sioux Tribe v. McDivitt,</i> 286 F.3d 1031 (8th Cir. 2002).....	28
<i>San Diego Cty. Gun Rights Comm. v. Reno,</i> 98 F.3d 1121 (9th Cir. 1996)	24
<i>Simon v. E. Ky. Welfare Rights Org.,</i> 426 U.S. 26 (1976)	24
<i>Skidmore v. Swift & Co.,</i> 323 U.S. 134 (1944).....	33
<i>Summers v. Earth Island Inst.,</i> 555 U.S. 448 (2009).....	18
<i>Susan B. Anthony List v. Driehaus,</i> 573 U.S. 149 (2014).....	16
<i>United States v. Mead Corp.,</i> 533 U.S. 218 (2001).....	32, 34
<i>Whitmore v. Arkansas,</i> 495 U.S. 149 (1990).....	17
STATUTES	
5 U.S.C. § 706.....	26, 28
21 U.S.C. § 601	3, 4, 26

21 U.S.C. § 602	1, 3, 29
21 U.S.C. § 603	3, 27
21 U.S.C. § 604	<i>passim</i>
21 U.S.C. § 621	4, 29
29 U.S.C. § 651	12, 30

RULES

Fed. R. Civ. P. 12.....	15, 25
-------------------------	--------

REGULATIONS

9 C.F.R. § 300.2	1, 4
9 C.F.R. pt. 309	4
9 C.F.R. § 309.1	5
9 C.F.R. pt. 310.....	4
9 C.F.R. § 310.1	5, 6

OTHER ADMINISTRATIVE MATERIALS

Revision Pursuant to Wholesome Meat Act, 35 Fed. Reg. 15552 (Oct. 3, 1970)	4
Cattle & Swine Post-Mortem Inspection Procedures and Staffing Standards, 47 Fed. Reg. 33673 (Aug. 4, 1982).....	4
Swine Post-Mortem Inspection Procedures and Staffing Standards, 50 Fed. Reg. 19900 (May 13, 1985).....	4
Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. 38806 (July 25, 1996)	6
HACCP-Based Meat and Poultry Inspection Concepts, 62 Fed. Reg. 31553 (June 10, 1997)	7
Modernization of Swine Slaughter Inspection, 83 Fed. Reg. 4780 (proposed Feb. 1, 2018).....	<i>passim</i>

Modernization of Swine Slaughter Inspection, 84 Fed. Reg. 52300 (Oct. 1, 2019)	<i>passim</i>
FSIS Directive 6100.1, https://www.fsis.usda.gov/wps/wcm/connect/2b2e7adc-961e-4b1d-b5937dc5a0263504/6100.1.pdf?MOD=AJPERESFSIS (July 24, 2014).....	5

INTRODUCTION

The Food Safety and Inspection Services (FSIS) of the U.S. Department of Agriculture (USDA) is charged with protecting consumer health and welfare by ensuring that the meat and meat food products sold to consumers are safe and unadulterated. *See* 21 U.S.C. § 602; 9 C.F.R. § 300.2(b)(1). In the mid-1990s, the agency began implementing a pilot program designed to realign its inspection resources to steer its food safety mission to focus more on combatting foodborne pathogens not visible on carcasses, and to place additional onus on swine (as well as poultry) slaughter establishments to ensure that federal meat inspectors are presented with healthier animals for ante-mortem inspection and carcasses with fewer visible defects for inspection on evisceration lines. Modernization of Swine Slaughter Inspection, 83 Fed. Reg. 4780, 4783 (proposed Feb. 1, 2018). This pilot program was tested in multiple swine slaughter facilities over the course of two decades. *Id.* at 4787. After many years of analysis and consideration, in 2019, FSIS promulgated the Modernization of Swine Slaughter Inspection rule with the goals of improving the effectiveness of swine slaughter inspection, making better use of the agency's resources, and removing unnecessary obstacles to industry innovation. *See* Modernization of Swine Slaughter Inspection, 84 Fed. Reg. 52300 (Oct. 1, 2019) (to be codified at 9 C.F.R. pts. 301, 309 & 310).

To achieve these goals, the rule establishes an optional New Swine Slaughter Inspection System (NSIS) for market hog establishments. *Id.* NSIS shifts FSIS resources toward offline inspection activities that are more effective in ensuring food safety, by requiring establishment employees to sort animals, carcasses, and parts prior to FSIS inspection. *Id.* Because this change allows FSIS inspectors to perform carcass-by-carcass inspections more efficiently,

establishments opting in to NSIS require fewer FSIS inspectors on evisceration lines, giving the agency flexibility to conduct more offline inspection activities. *Id.* Also due to increased online inspection efficiency, NSIS permits establishments to set their own line speeds based on their capabilities to maintain process control, with the caveat that FSIS personnel retain the ability to slow or stop the line if FSIS inspectors are unable to conduct effective carcass-by-carcass inspections. *Id.* FSIS predicts that the adoption of NSIS may reduce the prevalence of *Salmonella* on hog carcasses, resulting in fewer human illnesses. *Id.*

Plaintiffs, labor unions representing swine establishment workers, challenge the NSIS rule based on its purported effects on worker safety and its alleged failure to comply with FSIS's enabling statute, the Federal Meat Inspection Act of 1906 (FMIA), 21 U.S.C. § 601 *et seq.* But Plaintiffs both lack Article III standing to bring this lawsuit and fail to state a claim upon which relief may be granted. As an initial matter, Plaintiffs have not alleged injury to any specific member, nor can they show that any alleged future injury resulting from the rule is imminent, given that no establishment that employs their members has adopted—or has concrete plans to adopt—NSIS. Neither can they demonstrate that any such injury would result from the Government's actions, rather than the independent choices of those establishments that will ultimately determine whether and in what manner to opt in to NSIS. In addition, Plaintiffs fall outside the zone of interests of the FMIA, as the statute concerns food safety, not worker well-being. For the same reason, Plaintiffs have not stated a claim, as worker safety falls outside FSIS's statutory mandate under the FMIA, and the agency was thus under no requirement to consider such concerns in promulgating the NSIS rule. Finally, the D.C. Circuit considered and rejected an identical challenge to the pilot program testing the

NSIS features Plaintiffs challenge here, finding they complied with the FMIA. *See generally Am. Fed'n of Gov't Emps., AFL-CIO v. Veneman*, 284 F.3d 125 (D.C. Cir. 2002) (*AFGE II*).

For these reasons, as explained further below, Plaintiffs' complaint should be dismissed.

BACKGROUND

I. Statutory Background

Congress enacted the FMIA based on the finding that it is “in the public interest that the health and welfare of consumers be protected by ensuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged,” 21 U.S.C. § 602. In furtherance of the goal of protecting consumer health and safety, the FMIA charges the U.S. Secretary of Agriculture with, among other things, causing USDA inspectors to make “an examination and inspection of all amenable species before they shall be allowed to enter” any U.S. establishment that slaughters livestock for food products for use in commerce, and to set apart for slaughter any animal showing symptoms of disease. *Id.* § 603(a). Pursuant to the FMIA, USDA inspectors must also make “a post-mortem examination and inspection of the carcasses and parts thereof of all amenable species” prepared at any U.S. livestock slaughter or similar establishment for human consumption. *Id.* § 604. Inspectors are required to identify carcasses and parts as “condemned” if they are found to be adulterated. *Id.* An “adulterated” meat or meat product is one that, among other things, contains a poisonous or deleterious substance that may render it injurious to human health, is unfit for human consumption, or was prepared, packed, or held under unsanitary conditions that may make it harmful to human health. *Id.* § 601(m). When a meat or meat

product is condemned, the establishment must destroy it for food purposes under the supervision of USDA personnel. *Id.* § 604.

Consistent with these provisions, the FMIA requires the Secretary to appoint inspectors to examine all species covered by the Act and the “sanitary conditions” of all slaughter establishments handling such species, as well as “to make such rules and regulations as are necessary for the efficient execution” of the FMIA. *Id.* § 621. As relevant here, these provisions govern swine slaughter establishments. *See id.* § 601(j) & (w).

II. Regulatory Background

FSIS is responsible for implementing the FMIA and carrying out the USDA’s mission of protecting consumer health and welfare. *See* 9 C.F.R. § 300.2(b)(1); *see also, e.g., Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 456 (2012). Accordingly, FSIS has promulgated regulations to govern ante- and post-mortem examinations at swine slaughter establishments. *See, e.g.,* 9 C.F.R. pts. 309 & 310; Swine Post-Mortem Inspection Procedures and Staffing Standards, 50 Fed. Reg. 19900 (May 13, 1985); Cattle & Swine Post-Mortem Inspection Procedures and Staffing Standards, 47 Fed. Reg. 33673, 33673 (Aug. 4, 1982); *see also* Revision Pursuant to Wholesome Meat Act, 35 Fed. Reg. 15552, 15563–66 (Oct. 3, 1970). These regulations have also historically promoted the efficiency of USDA inspections and establishment production. *See* 50 Fed. Reg. at 19901; 47 Fed. Reg. at 33673. They do not address worker safety. *See id.*

A. The Traditional Inspection System

Under the traditional inspection system, FSIS regulations require federal inspectors to conduct ante-mortem inspections of all livestock offered for slaughter while at rest and in motion, and to direct establishment personnel to set apart animals showing visible signs of

disease or other condemnable conditions. *See* 9 C.F.R. § 309.1; 83 Fed. Reg. at 4783. In practice, however, under the traditional inspection system most market hog slaughter establishments voluntarily segregate animals before FSIS inspection. 83 Fed. Reg. at 4783. Establishments that currently take advantage of this option are required to document their segregation procedures, and FSIS personnel inspect each animal offered for slaughter after establishment personnel complete their segregation procedures. *See id.* FSIS inspectors are required to observe the establishment's voluntary ante-mortem segregation procedures at least once per month. FSIS Directive 6100.1, § XI(B)(5) (July 24, 2014), <https://www.fsis.usda.gov/wps/wcm/connect/2b2e7adc-961e-4b1d-b5937dc5a0263504/6100.1.pdf?MOD=AJPERESFSIS>.

With respect to post-mortem inspections, current regulations require FSIS inspectors to inspect each swine in three separate parts: head, viscera, and carcass. 9 C.F.R. § 310.1(b)(3); 83 Fed. Reg. at 4783. The traditional inspection system requires FSIS inspectors to identify localized defects correctable through trimming, and direct establishment employees to remove these defects. 83 Fed. Reg. at 4783. FSIS inspectors also look for signs of disease or contamination by performing incisions and palpations, in addition to other inspections using sight, smell, and touch, or “organoleptic inspections.” *Id.* Establishment employees do no pre-inspection sorting under the traditional inspection system, either to identify and remove correctable defects, or to flag carcasses and/or parts for an FSIS condemnation determination. *Id.* As such, the traditional inspection system requires that up to seven FSIS inspectors be assigned per line, per shift in large establishments. *Id.*

As a result of the time-intensive post-mortem sorting activities FSIS inspectors

perform under the traditional system, the maximum post-mortem inspection rate for market hogs is 1,106 heads per hour for seven online inspectors; it is lower when fewer inspectors are present. 9 C.F.R. § 310.1(b)(3); *see also* 83 Fed. Reg. at 4784. These rates are set, in part, based upon a consideration of the distance inspectors walk between work stations to conduct sorting activities, or whether a mirror eliminates the need for inspectors to turn a carcass to inspect both sides. *See id.*

B. A New Approach to Swine Slaughter Inspection Regulation

In 1996, FSIS launched an initiative designed to target its resources to address the public health risks associated with foodborne pathogens not detectable through traditional organoleptic inspection. *See* 83 Fed. Reg. at 4787; Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. 38806, 38807 (July 25, 1996). The agency first published a final rule requiring establishments to develop a system of preventive controls designed to ensure their products are safe, known as a hazard analysis and critical control point (HACCP) system. *See* 61 Fed. Reg. at 38806. The HACCP initiative marked a paradigm shift in FSIS's approach to fulfilling its statutory responsibilities, placing greater onus on establishments to ensure product safety while allowing them flexibility to determine the optimal way to comply with FSIS's food safety program. *See* 83 Fed. Reg. at 4787; 61 Fed. Reg. at 38808. FSIS recognized that fulfilling its food safety mission would require additional readjustment of FSIS and establishment responsibilities to align with the HACCP philosophy. 61 Fed. Reg. at 38808.

Accordingly, FSIS developed the HACCP-Based Inspection Models Project (HIMP), during which FSIS planned to design and test new inspection models in volunteer meat and

poultry slaughter establishments. *See* HACCP-Based Meat and Poultry Inspection Concepts, 62 Fed. Reg. 31553 (June 10, 1997). The HIMP pilot was created to, among other things, correct the “major problem” that “slaughter establishments have come to rely upon FSIS personnel to sort acceptable from unacceptable product” and “have no mandate or incentive to remove carcasses and parts prior to presentation for inspection.” *Id.* at 31555. FSIS observed that the traditional inspection system thus resulted in “FSIS’[s] resources [being used] inappropriately and inefficiently [to] . . . take on the industry’s responsibility for finding defects, identifying corrective actions, and solving production control problems.” *Id.* Moreover, as a result of this inefficient allocation of resources, the traditional inspection system did “not permit FSIS to allocate resources according to public health risk.” *Id.* The traditional system was designed when animal diseases detectable by organoleptic inspection were more prevalent. *Id.* Significant advances in disease control and the slaughtering of livestock at younger ages have since changed that. *Id.* Accordingly, the HIMP pilot systems were tested with the goals of improving food safety and inspection effectiveness, reducing the risk of foodborne illness, promoting industry innovation, and more efficiently utilizing FSIS resources. *See* 83 Fed. Reg. at 4787.

The HIMP pilot was initially rolled out in five market hog slaughter establishments and involved changes to both the ante- and post-mortem inspection processes.¹ *Id.* at 4787–88.

¹ FSIS originally proposed a HIMP model that did not involve an examination of each carcass by FSIS inspectors. *See Am. Fed’n of Gov’t Emps., AFL-CIO v. Glickman*, 215 F.3d 7, 11 (D.C. Cir. 2000) (*AFGE I*). The D.C. Circuit found this approach inconsistent with the requirements of the FMIA. *See id.* In response, FSIS modified HIMP, and the D.C. Circuit subsequently held that the revised HIMP model complied with the FMIA because it involved an examination of each hog head, carcass, and viscera by FSIS inspectors. *See AFGE II*, 284 F.3d at 130–31.

The new ante-mortem process was very similar to the voluntary segregation system many market hog establishments had already implemented. *Id.* Establishment personnel would sort animals prior to FSIS inspection, disposing of deceased animals and those suspected of having certain disorders. *Id.* FSIS inspectors would then examine all animals offered for slaughter following establishment sorting, directing establishment personnel to remove any additional animals suspected of having condemnable conditions. *Id.* FSIS veterinarians then examined all animals in both the establishment-sorted “Subject” pens and FSIS-sorted “U.S. Suspect” pens to determine if any animals must be condemned. *Id.* FSIS inspectors would observe establishment sorting procedures at least twice per shift. *Id.*

Under HIMP, post-mortem FSIS inspectors still visually inspected the head, carcass, and viscera of each hog at fixed stations on the evisceration line. *Id.* Prior to FSIS inspection, however, establishment personnel sorted carcasses and parts, trimmed correctible defects, and marked carcasses and parts for disposal under FSIS supervision. *Id.* This made FSIS online inspection more efficient, as most removable defects were corrected prior to FSIS inspection. *Id.* The increased efficiency freed up FSIS inspectors to conduct more offline inspections than under the traditional inspection system, including food-safety-related verification activities. *Id.* Also as part of the HIMP pilot, participating market hog slaughter establishments were permitted to set their own evisceration line speeds, including in some instances to exceed the existing maximum line speed, provided that FSIS personnel monitored the establishment’s ability to maintain process control. *See id.* at 4796.

In 2014, FSIS prepared a written report evaluating the HIMP models tested in market hog slaughter establishments between 2006 and 2013. *See* 83 Fed. Reg. at 4788–89. The report

included an evaluation of the relative performance of establishments that participated in HIMP and those that did not. *Id.* at 4789. Overall, the report found that FSIS inspectors performed more offline verification activities in HIMP establishments while maintaining food safety defect levels equal to or lesser than those at traditional establishments. *Id.* at 4789–90. FSIS also prepared a risk assessment that suggested a correlation between an increase in FSIS offline procedures in market hog establishments and a reduction in the prevalence of *Salmonella* in market hog carcasses. *Id.* at 4791.

C. Modernization of Swine Slaughter Inspection: The Proposed Rule

Based on the results of the HIMP pilot, on February 1, 2018, FSIS published a notice of proposed rulemaking (NPRM), proposing to amend the regulations governing swine slaughter inspections to establish an optional new inspection system—NSIS—for market hog slaughter establishments. 83 Fed. Reg. at 4780. The goals were to reduce pathogens in pork products; improve the effectiveness of FSIS inspection; more efficiently utilize FSIS resources; and to allow establishments the flexibility to innovate. *Id.* The key elements of NSIS include three features tested during the HIMP pilot: (1) requiring establishment employees to perform ante- and post-mortem sorting activities prior to FSIS inspection; (2) shifting FSIS resources to reduce the number of online inspectors to a maximum of three per line, per shift and increase offline inspection activities; and (3) revoking maximum line speeds and permitting establishments to set their own line speeds based on their ability to maintain process control. *Id.* at 4781.

As explained in the NPRM, FSIS found that establishments that implemented these features under HIMP performed at least as well as comparable market hog slaughter

establishments and received more offline inspections, which are directly related to food safety. *Id.* at 4789–90. FSIS also noted that HIMP establishments operated at an average line speed of 1,099 heads per hour—slower than the maximum speed allowed under the traditional inspection system—and that line speeds varied from 885 heads per hour to 1,295 heads per hour.² *Id.* at 4796. This variety resulted from the fact that multiple factors inform whether an establishment is able to increase its line speeds, including equipment, animal size, herd condition, and number of employees. *Id.*

The NPRM also reported on data available with respect to the effects of line speed on establishment employee safety. *Id.* FSIS determined that five HIMP and 29 traditional market hog slaughter facilities had voluntarily submitted injury rate data to the Occupational Safety and Health Administration (OSHA). *Id.* A comparison of these data showed that HIMP establishments had a lower mean number of establishment worker injuries than traditional establishments when analyzed under three OSHA measures.³ *Id.* FSIS also recognized, however, that “factors other than line speed may affect injury rates (*e.g.*, automation and number of sorters per line)” and requested comments on “the effects of faster line speeds on worker safety.” *Id.*

FSIS received over 83,000 comments in response to the NPRM. 84 Fed. Reg. at 52304.

² Although the average line speed at HIMP establishments was slower than the maximum speed allowed under the traditional inspection system, it was approximately 12.49 percent faster than the line speed at comparable traditional establishments. 84 Fed. Reg. at 52335.

³ The data FSIS utilized in this analysis, although not included in the NPRM, was and is publicly available: OSHA’s Establishment Specific Injury and Illness Data is posted on OSHA’s website, and establishment level production volume information is posted on FSIS’s website. *See* 84 Fed. Reg. at 52305.

Among these were comments from worker advocacy organizations and labor unions asserting that revoking maximum line speeds would increase risks to worker health and safety. *Id.* at 52314. These comments pointed to documents published by, among others, OSHA explaining that repetitive stress injuries were common among workers employed in the meatpacking industry and recommending reduction of line speeds as a means of decreasing injury rates. *See id.* FSIS also received comments expressing concern that the establishment pre-sorting required under the NSIS violated the FMIA. *See id.* at 52311–12.

D. Modernization of Swine Slaughter Inspection: The Final Rule

On October 1, 2019, FSIS published the final Modernization of Swine Slaughter Inspection rule, effective December 2, 2019. 84 Fed. Reg. at 52300. The final rule adopted, in relevant part, the key components of the proposed optional NSIS discussed *supra*.⁴ *See id.*; *supra* at p. 9. The final rule also reiterated that, because establishment pre-sorting procedures would result in FSIS inspectors being presented with healthier animals and carcasses with fewer defects, FSIS inspections would be more efficient, permitting fewer inspectors to perform the same work. 84 Fed. Reg. at 52300. It simultaneously made clear that “FSIS inspectors will still be stationed on the evisceration line and these inspectors will continue to inspect every head, viscera, and carcass as required by the FMIA.” *Id.* at 52311.

Although NSIS permits establishments that opt in to set their own line speeds without a maximum cap, FSIS inspectors retain the authority to stop or slow the line if necessary. *Id.*

⁴ The final rule includes two mandatory provisions that apply to all swine slaughter establishments: development and implementation of sanitary dressing and microbiological sampling plans. *See* 84 Fed. Reg. at 42322–23. Plaintiffs do not challenge these universal requirements.

at 52300. Agency personnel may direct an establishment to reduce line speeds when, in their assessment, a carcass-by-carcass inspection cannot be performed at the speeds presented, or the establishment is not maintaining process control. *Id.* at 52312. The ability to maintain process control and factors such as equipment, animal size, herd condition, and number of employees, *see* 83 Fed. Reg. at 4796, as well as consumer demand for pork products, *see* 84 Fed. Reg. at 52335, 52342–43, inform establishments’ decisions as to how fast the line may go.

In the final rule, FSIS addressed various comments regarding worker safety. *See id.* at 52314–15. Although the agency “agree[d] that safe working conditions in swine slaughter establishments are important,” it explained that FSIS “has neither the authority nor the expertise to regulate issues related to establishment worker safety.” *Id.* at 52315. FSIS pointed out that the FMIA authorizes it to protect consumer health and welfare, and that under the Occupational Safety and Health Act of 1970, 29 U.S.C. § 651 *et seq.*, OSHA has the statutory and regulatory authority to assure safe working conditions and promote workplace safety. *Id.* Nevertheless, FSIS acknowledged efforts to cooperate with OSHA to promote the latter’s workplace safety mission. *Id.* For example, FSIS worked with OSHA to develop a poster for display providing information on worker injuries and conditions, and the right to report these issues without retaliation. *Id.* The rule requires NSIS establishments to submit yearly attestations that they have a program to monitor and document work-related conditions, which FSIS will forward to OSHA for its use. *Id.* In addition, FSIS has a longstanding Memorandum of Understanding with OSHA regarding training FSIS workers to recognize workplace hazards and refer them to OSHA. *Id.*

Also in the final rule, FSIS assessed anticipated costs and benefits, as required under

Executive Orders 12866 and 13563. *See* 84 Fed. Reg. at 52320–41. As part of this required analysis, FSIS predicted that, due to economic constraints, only certain market hog establishments would opt in to NSIS. *Id.* at 52322. Forty such establishments existed in 2016 (including the five HIMP establishments). *Id.* But FSIS does not know whether any of these establishments will ultimately opt in to NSIS. *See id.* In fact, FSIS considered multiple possible adoption scenarios in its cost-benefit analysis, including that only the five HIMP establishments opt in to NSIS. *Id.* at 52339. For those establishments that opt in, FSIS predicts that the costs of NSIS will include hiring new employees to perform the additional tasks required of establishment personnel—between 6 and 11 additional workers per shift, per line for large establishments—and training those new employees. *Id.* at 52324. FSIS expects that the benefits may include a lower prevalence of *Salmonella*, and thus fewer human illnesses. *Id.* at 52332. FSIS also posits that the final rule will reduce the regulatory burden on establishments, increase their compliance with sanitation regulations, and improve animal welfare by increasing offline monitoring of humane handling procedures. *Id.* at 52335–36.

III. Procedural Background

Plaintiffs filed this suit against Defendant USDA (the Government) on October 7, 2019. *See generally* Compl., ECF No. 1. Plaintiffs are an international labor union and three of its local affiliates: United Food and Commercial Workers Union, Local No. 663 (Local 663); United Food and Commercial Workers Union, Local No. 440 (Local 440); United Food and Commercial Workers Union, Local No. 2 (Local 2); and United Food and Commercial Workers Union, AFL-CIO, CLC (collectively, Plaintiffs or UFCW). *Id.* ¶¶ 10–13. Plaintiff unions represent swine slaughter establishment workers. *Id.* ¶ 1.

Local 663 allegedly has approximately 1,900 members who work at the JBS USA swine slaughter establishment in Worthington, Minnesota, which Plaintiffs allege is one of the establishments that FSIS has assumed will opt in to NSIS for the purpose of its cost-benefit analysis; currently operates its evisceration line at the maximum line speed; and “has recently begun the process of adding coolers and expanding the kill floor and loading docks, which would allow it to increase the line speed.” *Id.* ¶ 10.

Local 440 allegedly has approximately 1,100 members who work at the Smithfield swine slaughter establishment in Denison, Iowa, which Plaintiffs allege is one of the establishments that FSIS has assumed will opt in to NSIS for the purpose of its cost-benefit analysis; currently operates its evisceration line at the maximum line speed; and its “[p]lant management has expressed a desire to remodel its facilities in a manner that would allow it to increase the line speed.” *Id.* ¶ 11.

Local 2 purportedly represents approximately 2,500 workers at Triumph Foods in St. Joseph, Missouri, and approximately 2,100 workers at Seaboard Foods in Guymon, Oklahoma, both of which Plaintiffs allege currently operate their evisceration lines at the maximum line speed, *id.* ¶ 12, and are among the establishments that FSIS has assumed will opt into NSIS for the purpose of its cost-benefit analysis, *id.* ¶ 70. Plaintiffs allege that Triumph Foods’ “current layout indicates it has the ability to increase its line speeds,” and that Seaboard Foods’ “management in Guymon has indicated it plans to expand its facilities in a manner that would allow it to increase the line speed.” *Id.* ¶ 12. In all, Plaintiffs allege that UFCW has approximately 31,000 members who work at 17 of the establishments that FSIS assumed will implement NSIS for the purpose of its cost-benefit analysis. *Id.* ¶ 13.

Plaintiffs assert that the rule harms their members by “permitting . . . employers to increase line speeds without limit, putting their members at [a] substantially increased risk of injury,” *id.* ¶ 72, and by reducing the number of online FSIS inspectors, which purportedly reduces the possibility that an inspector will observe dangerous conditions and halt the line to protect worker safety, *id.* ¶ 73. They allege three causes of action pursuant to the Administrative Procedure Act (APA), 5 U.S.C. § 551 *et seq.* *Id.* ¶¶ 74–83. First, Plaintiffs claim that USDA arbitrarily and capriciously failed to consider comments that faster line speeds subject workers to a greater risk of injury (Count One). *Id.* ¶¶ 74–77. Second, Plaintiffs assert that the final rule’s reduction of online FSIS inspectors, together with the elimination of maximum line speeds, violates the FMIA’s requirement that FSIS conduct a critical appraisal of each animal on the line (Count Two). *Id.* ¶¶ 78–80. Third, Plaintiffs claim that USDA acted arbitrarily and capriciously by failing to provide an adequate rationale for reducing the number of FSIS online inspectors, insofar as it did not acknowledge comments discussing worker safety (Count Three). *Id.* ¶¶ 81–83.

ARGUMENT

I. Plaintiffs Lack Standing to Bring this Action.

A. Standards of Review

To satisfy Article III’s case-or-controversy requirement, a plaintiff has the burden of establishing standing to sue. *See, e.g., Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992) (plurality opinion). “[S]tanding is a jurisdictional prerequisite that must be resolved before reaching the merits of a suit.” *City of Clarkson Valley v. Mineta*, 495 F.3d 567, 569 (8th Cir. 2007). A motion under Federal Rule of Civil Procedure 12(b)(1) can constitute either a “facial

attack” or a “factual attack.” *Osborn v. United States*, 918 F.2d 724, 729 n.6 (8th Cir. 1990). In a facial attack, such as this one, “the court restricts itself to the face of the pleadings,” as well as matters of public and administrative record incorporated by reference in the complaint. *Id.*; see also *Deerbrook Pavilion, LLC v. Shalala*, 235 F.3d 1100, 1102 (8th Cir. 2000).

“[T]he irreducible constitutional minimum of standing contains three elements”: injury, causation, and redressability. *Defs. of Wildlife*, 504 U.S. at 560. Where, as here, an association files suit on behalf of its members, see Compl. ¶¶ 72–73, it has standing only where “its members would otherwise have standing to sue in their own right, the interests at stake are germane to the organization’s purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit,” *Iowa League of Cities v. EPA*, 711 F.3d 844, 869 (8th Cir. 2013) (quoting *Friends of Earth, Inc. v. Laidlaw Env’tl Servs., Inc.*, 528 U.S. 167, 181 (2000)). Associational standing is lacking unless the plaintiff association shows “one or more of [its] members would . . . be directly affected” by the defendant’s actions. *Defs. of Wildlife*, 504 U.S. at 563 (internal quotation marks and citation omitted).

B. Plaintiffs’ Alleged Injuries Are Remote and Speculative.

Demonstrating injury in fact requires a plaintiff to show harm that is “concrete, particularized, and actual or imminent.” *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 409 (2013) (quoting *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 149 (2010)). Where the alleged injury has not yet occurred, the threatened injury must be “certainly impending” or there must be a “substantial risk that the harm will occur.” *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014) (quoting *Clapper*, 568 U.S. at 409, 414 n.5); see also *Defs. of Wildlife*, 504 U.S. at 564 n.2 (acknowledging the “settled requirement that the injury complained of be, if not actual, then

at least *imminent*’). “[A]llegations of *possible* future injury’ are not sufficient.” *Clapper*, 568 U.S. at 409 (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990)).

Applying these principles, the D.C. Circuit previously held that plaintiffs lacked standing to challenge the rule implementing FSIS’s optional new poultry inspection system (NPIS)—which is substantially similar to NSIS—based on its determination that the risk of future harm was not substantial enough to constitute injury in fact. *See Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 915–18 (D.C. Cir. 2015). There, individual consumers and a consumer watchdog group alleged that inadequacies in the NPIS—including the reduced number of FSIS inspectors and the increase in evisceration line speeds—would increase the risk of foodborne illnesses. *Id.* at 915. Plaintiffs also pointed to purported flaws in the poultry HIMP studies. *Id.* Nevertheless, that court found these allegations failed to demonstrate a substantial increase in the risk of foodborne illness, as opposed to the traditional inspection system, and the injury-in-fact requirement was therefore lacking. *See id.* at 915–16; *accord Am. Fed. Gov’t Emps., AFL-CIO v. Vilsack*, 672 F. App’x 36 (D.C. Cir. 2016) (per curiam) (unpublished)

Although Plaintiffs’ alleged injuries differ here, they are no more concrete than those the D.C. Circuit rejected in *Food and Water Watch*. Plaintiffs’ principal alleged harm is that NSIS will place their establishment-employee members at an increased risk of physical injury because the optional system (1) removes maximum line speed limits and (2) reduces the number of FSIS inspectors present on the line. Compl. ¶¶ 72–73. Plaintiffs’ allegations fail to establish that these two features of NSIS create a substantial increase in the risk of injury to Plaintiffs’ members, as compared to the risk under the traditional inspection system, for

multiple reasons.

First and foremost, Plaintiffs fail to include concrete allegations regarding the likelihood of injury to any individual member. Although they generally assert that numerous members work at swine slaughter establishments likely to adopt NSIS, Plaintiffs do not specify their members' roles at these establishments, other than alluding to the fact that some Local 663 and Local 2 members work on evisceration lines. *See Compl. ¶¶ 10–13, 33–35.* But the complaint neither identifies any individual member of any Plaintiff union, nor explains with particularity how or why the rule would put that person at a substantially increased risk of harm. In addition, Plaintiffs nowhere allege that the claims asserted in Count Two—alleged violations of the FMIA, which they do not assert have any bearing on worker safety—harm their members specifically, as opposed to stating the type of generalized grievance that is not sufficiently particularized to constitute Article III injury. *See Summers v. Earth Island Inst.*, 555 U.S. 448, 494 (2009) (“generalized harm . . . will not alone support standing”); *Defs. of Wildlife*, 504 U.S. at 556. Plaintiffs thus have not fulfilled the requirement to “show that at least one of [their] members would have individual standing.” *Owner-Operator Indep. Drivers Ass’n v. U.S. Dep’t of Transp.*, 831 F.3d 961, 967 (8th Cir. 2016).

Second, NSIS is optional, and it is unknown whether any of the establishments at which Plaintiffs’ members are employed will adopt the new inspection system. *See* 84 Fed. Reg. at 52322. Establishments that opt not to implement, or do not qualify for, NSIS will continue to operate under the traditional inspection system, and the status quo regarding line speeds and FSIS inspectors will remain unchanged. *See id.* at 52301. To be sure, for the purpose of cost-benefit analysis, FSIS determined the number of market hog establishments that are

eligible to participate in NSIS and, taking into account economic constraints, assumed that 40 market hog establishments would opt in. *Id.* But it also considered alternative scenarios, including that only the five HIMP establishments—and *no* additional ones—adopt NSIS. *Id.* at 52339. FSIS has no control over these private establishments’ choices, and the agency made clear that the provisions at issue “apply to only those establishments that choose to participate in the optional NSIS.” *Id.* at 52301. Although Plaintiffs allege that certain of their members are employed by establishments that FSIS assumed, for the purpose of analysis, would adopt NSIS, Compl. ¶¶ 69–70, there is no concrete allegation that any of these establishments will *actually* opt in. If none of these establishments adopts NSIS, Plaintiffs’ members cannot suffer injury from NSIS. Because the rule allows, but does not require, market hog establishments to adopt NSIS, and if and when these establishments may adopt NSIS is unknown, Plaintiffs have not shown a “substantial risk” of injury resulting from the rule. *See Clapper*, 568 U.S. at 412 (“[B]ecause § 1881a at most *authorizes*—but does not *mandate* or *direct*—the surveillance that respondents fear, respondents’ allegations are necessarily conjectural.”).

Third, any establishment that ultimately adopts NSIS may choose not to increase its line speeds above the current maximum of 1,106 head per hour. *See* 84 Fed. Reg. at 52314. Indeed, establishments that participated in the HIMP pilot operated at an average line speed of 1,099 head per hour, and line speeds in these establishments varied from 885 to 1,295 head per hour.⁵ *Id.* Whether an establishment increases its line speed depends on multiple variables,

⁵ Although the average line speed at HIMP establishments was approximately 12.49 percent faster than at comparable establishments operating under the traditional system, 84 Fed. Reg. at 52335, it was still below the maximum line speed under the traditional system, *see id.* at 52314.

including internal constraints such as equipment, animal size, herd condition, and number of employees, *see* 83 Fed. Reg. at 4796, and external factors like consumer demand, *see* 84 Fed. Reg. at 52335, 52342–43. Thus, the revocation of maximum line speeds under NSIS will not necessarily result in establishments increasing their line speeds above the former upper limit.

See id.

Further, although Plaintiffs allege that certain of the establishments that employ their members have the potential ability to increase line speeds based on their current or possible future layouts, Compl. ¶¶ 10–12, they do not allege that any of the establishments have concrete plans to increase their line speeds above the current maximum. And the choice of whether to increase line speeds will likely depend on factors beyond the facilities’ capabilities. *See* 83 Fed. Reg. at 4796; 84 Fed. Reg. at 52335, 52342–43. Even assuming that increased line speeds would substantially increase the risk of worker injury—which, as explained *infra*, is an invalid assumption in these circumstances—Plaintiffs’ speculative allegation that their members will be at an increased risk of injury due to increased line speeds cannot establish Article III injury.

Fourth, Plaintiffs’ allegations do not show a substantially increased risk of injury to their members even assuming the relevant establishments increase their line speeds above the current maximum. Adoption of NSIS is expected to result in significant changes to establishment workers’ jobs, including new roles with new responsibilities, the hiring of additional employees to fulfill these roles, and facility upgrades and/or line reconfigurations to support new establishment duties. *See* 84 Fed. Reg. at 52324–25. FSIS has recognized that factors such as automation and number of employees per line may affect worker injury rates.

83 Fed. Reg. at 4796. Yet Plaintiffs' allegations of increased injury risk appear dependent upon the assumption that an increase in line speeds in NSIS establishments will result in the same number of establishment employees performing the same tasks, in the same space, at an increased rate of speed. *See, e.g.*, Compl. ¶ 28 ("Studies have repeatedly shown that increased line speed rates lead to increased rates of these injuries due to the increase in the number of repetitive forceful motions required."); *id.* ¶ 29 ("Risk of these injuries also increases when line speeds increase, as workers are placed closer together and/or are using sharp knives more quickly.").

That assumption is unsupported. To the contrary, FSIS predicted that establishments adopting NSIS would hire more employees and may also reconfigure or update their facilities. 84 Fed. Reg. at 52324–25. And FSIS's analysis of the data available concerning worker injury rates at HIMP establishments—the only establishments that have implemented an inspection system like NSIS—showed that HIMP establishments had a lower mean number of injuries than establishments operating under the traditional inspection system. 83 Fed. Reg. at 4796.

Although Plaintiffs take issue with this analysis, *see* Compl. ¶ 47, they offer no concrete allegations regarding the effects of NSIS on worker safety. Instead, Plaintiffs' allegations demonstrate the prevalence of worker injuries under the traditional inspection system. *See id.* ¶¶ 27–29, 33–35. And the fact that the only study available regarding injury rates under NSIS shows that they are actually lower than injury rates under the traditional inspection system underscores that Plaintiffs' claim of future injuries as a result of NSIS is entirely speculative. *See Food & Water Watch*, 808 F.3d at 915.

Finally, Plaintiffs' assertion that their members will be harmed by the reduction in the

number of online FSIS inspectors is unsupported. Plaintiffs' only allegation connecting the number of inspectors to worker safety is the conclusory assertion that fewer online FSIS inspectors will make those present on the line "less likely to observe dangerous conditions and to halt the line when necessary to protect workers." Compl. ¶ 73. But Plaintiffs nowhere assert that FSIS inspectors are expected to, or do in practice, act to protect workers under the traditional inspection system. To the contrary, the complaint alleges that swine slaughter workers experience frequent injuries under the traditional inspection system, the number of online FSIS inspectors notwithstanding. *See, e.g., id.* ¶¶ 26–29, 33–35. Of course, as a matter of human decency, an FSIS inspector (or any other observer) would surely stop the line were a catastrophic injury to occur. But FSIS inspectors are not, under the traditional inspection system or NSIS, charged with overseeing establishment employee safety. Cf. *Dawkins ex rel. Estate of Dawkins v. United States*, 226 F. Supp. 2d 750, 757 (M.D.N.C. 2002) (holding that, in carrying out food safety measures, FSIS was not responsible for ensuring establishment workers' safety). Instead, pursuant to the FMIA and its implementing regulations, FSIS inspectors' role on the line is to conduct a carcass-by-carcass inspection to determine fitness for human consumption. *See* 21 U.S.C. § 604. Because FSIS inspectors are not charged with protecting worker safety, and there is no concrete allegation that they do so in practice, Plaintiffs' claim that a reduction in the number of online FSIS inspectors will increase the risk of worker injury is, like their other claims of injury, hypothetical. *See Food & Water Watch*, 808 F.3d at 916.

C. Plaintiffs' Alleged Injuries Are Not Fairly Traceable to the Government's Actions.

Not only do Plaintiffs fail to allege an imminent injury, they also cannot demonstrate

that any alleged injury would be caused by the Government's actions. Where "the plaintiff is not himself the object of the government action or inaction he challenges," standing is "ordinarily substantially more difficult to establish." *Defs. of Wildlife*, 504 U.S. at 562 (internal quotation marks and citation omitted). This is because causation "hinge[s] on the response of the regulated (or regulable) third party to the government action or inaction." *Id.* Therefore, in such circumstances, an "essential element[] of standing depends on the unfettered choices made by independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume to either control or predict." *Id.* (internal quotation marks and citation omitted). It is a plaintiff's burden to show that the regulated third party has or will make choices in a manner that results in causation. *Id.*

For three reasons, Plaintiffs have not met their burden to show that FSIS's actions will cause swine slaughter establishments—the third parties subject to the rule—to make choices that will result in injury to Plaintiffs' members. First, as discussed, for the harms Plaintiffs have alleged to occur, the establishments that employ Plaintiffs' members must, at a minimum, choose both to participate in NSIS and to increase their evisceration line speeds above the current maximum. The new rule does not require either choice; it merely permits them. *See* 84 Fed. Reg. at 52300. Plaintiffs do not allege (because they cannot) that the establishments have adopted or will adopt NSIS, merely that they are eligible to do so. *See* Compl. ¶¶ 10–13, 70–71. The same applies to increasing line speeds—Plaintiffs allege only that certain establishments that employ their members are, or may be in the future, capable of increasing line speeds. *See id.* ¶¶ 10–12. Courts have long held that third-party actions are not fairly traceable to a regulation where that regulation permits, but does not require, the third party to

take the action that directly results in a plaintiffs' injury. *See, e.g., Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 42–43 (1976) (holding that plaintiffs' injuries were not traceable to tax ruling that allegedly "encouraged" certain actions but did not require them); *Binno v. Am. Bar Ass'n*, 826 F.3d 338, 345 (6th Cir. 2016) (holding that plaintiff law student's injuries were not traceable to defendant bar organization where it permitted but did not mandate law schools' use of allegedly discriminatory test); *Grocery Mfrs. Ass'n v. EPA*, 693 F.3d 169, 177 (D.C. Cir. 2012) (finding that plaintiff's alleged harms were not traceable to governmental actions where the approval of a new fuel "d[id] not force, require, or even encourage . . . introduc[tion] [of] the new fuel" but "simply permit[ted]" it); *Lane v. Holder*, 703 F.3d 668, 674 (4th Cir. 2012) (holding that traceability was lacking where firearm regulation did not require middlemen to charge fees that caused plaintiffs' alleged injuries).

Second, even assuming these establishments were to adopt NSIS and increase their line speeds above the current maximum, they retain complete discretion as to whether to take steps such as hiring more employees, reconfiguring their facilities, or increasing automation on the evisceration line. Each such decision, none of which NSIS mandates, could potentially affect employee injury rates. *See* 83 Fed. Reg. at 4796. Traceability is lacking where it is unclear whether a plaintiff's injury resulted from a challenged governmental action or other distinct potentially causal factors. *See Simon*, 426 U.S. at 42–43 (finding it "purely speculative" whether plaintiffs' injuries resulted from third parties' response to challenged tax ruling or from factors other than tax implications); *San Diego Cty. Gun Rights Comm. v. Reno*, 98 F.3d 1121, 1130 (9th Cir. 1996) (holding that plaintiffs' economic injury was not traceable to challenged legislation where "the Act [was] neither the only relevant piece of legislation nor the sole factor affecting

the price”). In these two ways, the uncertain independent decisionmaking of third parties breaks the chain of causation between FSIS’s adoption of the new rule and any future injuries Plaintiffs’ members might suffer.

Finally, were the establishments that employ Plaintiffs’ members both to adopt NSIS and to increase their line speeds, Plaintiffs still could not demonstrate that any injury to their members was caused by these choices. The complaint alleges that, under the current system, “[m]eatpacking workers have the highest rate of occupational illness of any private industry in the country,” Compl. ¶ 27, and that Plaintiffs’ members often suffer both repetitive motion and laceration injuries as a result of their work on slaughter lines, *id.* ¶¶ 33–35. As explained, the only analysis of injury rates under working conditions comparable to those under NSIS—imperfect or not—suggests that injury rates under NSIS will be lower than those under the traditional inspection system. *See* 83 Fed. Reg. at 4796. It is therefore pure speculation that any future worker injuries that may occur under NSIS will result from certain features of NSIS, rather than from the well-documented occupational hazards that traditionally accompany swine slaughter employment. These preexisting dangers are an equally, if not more, probable cause of any future injuries to Plaintiffs’ members. *Cf. Food & Water Watch*, 808 F.3d at 918.

II. Plaintiffs Fail to State a Claim Upon Which Relief Can Be Granted.

A. Standards of Review

Dismissal of a complaint is warranted for “failure to state a claim upon which relief can be granted.” Fed. R. Civ. P. 12(b)(6). “To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim for relief that is plausible on its face.” *McChesney v. FEC*, 900 F.3d 578, 583 (8th Cir. 2018) (quoting *Ashcroft v. Iqbal*, 556

U.S. 662, 678 (2009) (internal quotation marks omitted)).

The FMIA does not provide for a private right of action, *see generally* 21 U.S.C. § 601 *et seq.*, but the APA “provides for judicial review of agency action,” *Cent. S.D. Co-op. Grazing Dist. v. Sec'y of USDA*, 266 F.3d 889, 894 (8th Cir. 2001). In addition to demonstrating Article III standing, a plaintiff suing under the APA has the burden to show that “[t]he interest he asserts [is] arguably within the zone of interests to be protected or regulated by the statute that he says was violated.” *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 224 (2012) (internal quotation marks and citation omitted). The “zone of interests” test thus serves “as a limitation on the cause of action for judicial review conferred by the [APA].” *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 129 (2014). Whether a plaintiff’s claim falls within the zone of interests “is determined by reference to the particular provision of law upon which the plaintiff relies.” *Cent. S.D. Co-op. Grazing Dist.*, 266 F.3d at 896.

As relevant here, to state a claim under the APA, a plaintiff must plausibly allege that a challenged agency action was “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A). Courts must uphold agency decisionmaking under the arbitrary-and-capricious standard unless

the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Cent. S.D. Co-op. Grazing Dist., 266 F.3d at 894 (quoting *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983)).

Plaintiffs allege that USDA (1) acted arbitrarily and capriciously by failing to consider the effects of increased line speeds on worker safety, Compl. ¶¶ 74–77; (2) acted contrary to law because NSIS purportedly violates the requirements of the FMIA, *id.* ¶¶ 78–80; and (3) acted arbitrarily and capriciously by failing to provide an adequate rationale for reducing the number of FSIS online inspectors and by not addressing its asserted impact upon worker safety, *id.* ¶¶ 81–83.

Because Plaintiffs’ claims fall outside the zone of interests of the FMIA, and each fails as a matter of law, dismissal pursuant to Rule 12(b)(6) is warranted.

B. Plaintiffs’ Alleged Injuries Fall Outside the FMIA’s Zone of Interests.

Although the zone-of-interests test “is not meant to be especially demanding,” it bars suit “when a plaintiff’s interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit.” *Patchak*, 567 U.S. at 225 (internal quotation marks and citation omitted). The relevant statutory provisions at issue here are Sections 603(a) and 604 of the FMIA. *See* Compl. ¶¶ 18–19 (quoting 21 U.S.C. §§ 603(a), 604). Those provisions respectively require USDA to conduct ante-mortem inspections “[f]or the purpose of preventing the use in commerce of meat and meat food products which are adulterated,” 21 U.S.C. § 603(a), and post-mortem inspections “[f]or the purposes hereinbefore set forth,” *id.* § 604. These statutes are thus clearly intended to protect consumers by ensuring meat entering the market is safe and unadulterated.

Plaintiffs’ organizations, in contrast, represent the interests of workers, and the focus of their claims is establishment worker safety. *See* Compl. ¶¶ 10–13, 74–83. There is nothing

within either of the statutory provisions pursuant to which Plaintiffs bring their claims—nor in the FMIA as a whole—that would suggest Congress intended workers to bring suit under them to advance worker safety. And Plaintiffs’ interests in worker safety are unrelated to the statutory purpose of food safety. As such, they cannot meet their burden of showing that they fall within the statutes’ zone of interests. *See Rosebud Sioux Tribe v. McDivitt*, 286 F.3d 1031, 1037–39 (8th Cir. 2002) (holding that plaintiff suing in furtherance of its economic interests fell outside the zone of interests of statutes intended to protect Native American and environmental interests); *Cent. S.D. Co-op. Grazing Dist.*, 266 F.3d at 895–97 (same).

C. As a Matter of Law, USDA Does Not Have the Statutory Mandate to Regulate Worker Safety under the FMIA.

Counts One and Three both allege that USDA acted arbitrarily and capriciously by failing to consider worker safety in relation to different aspects of NSIS—namely, the elimination of maximum line speeds (Count One) and the reduction of online FSIS inspectors (Count Three). Both of these claims fail as a matter of law because FSIS does not have the statutory mandate to regulate worker safety in implementing the FMIA.

It is a fundamental principle of administrative law that agencies are required to exercise their regulatory authority within the bounds of congressional authorization. *See, e.g.*, 5 U.S.C. § 706(2)(C); *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988) (“It is axiomatic that an administrative agency’s power to promulgate legislative regulations is limited to the authority delegated by Congress.”); *Iowa League of Cities*, 711 F.3d at 876 (observing that “the APA authorizes courts to strike down as ultra vires agency rules promulgated without valid statutory authority”). “An agency need not consider all policy alternatives in its decision-making” or “pursue policy alternatives that are contrary to the pertinent statutory goals.” *Cent. S.D. Co-*

op. Grazing Dist., 266 F.3d at 897. Similarly, an agency is not required to analyze in detail every comment it receives in response to an NPRM. It is instead entitled to focus on “significant” comments which “raise points relevant to the agency’s decision and which, if adopted, would require a change in an agency’s proposed rule.” *Home Box Office, Inc. v. FCC*, 569 F.2d 9, 35 n.58 (D.C. Cir. 1977) (per curiam). The decision as to which comments to focus on is evaluated under a reasonableness standard. *See id.* An agency’s failure to consider comments is not grounds for setting aside an agency decision “[i]f the comments ignored by the agency would not bear on the agency’s ‘consideration of the relevant factors.’” *Altera Corp. & Subsidiaries v. Comm’r*, 926 F.3d 1061, 1081 (9th Cir. 2019) (quoting *Am. Mining Congress v. EPA*, 965 F.2d 759, 771 (9th Cir. 1992)). And even the agency’s obligation to respond to “significant” comments is not “particularly demanding.” *Pub. Citizen, Inc. v. FAA*, 988 F.2d 186, 197 (D.C. Cir. 1993).

The FMIA authorizes the Secretary of Agriculture to “make such rules and regulations as are necessary,” 21 U.S.C. § 621, “to protect the health and welfare of consumers,” as well as to “prevent and eliminate burdens upon . . . commerce” by “assuring that meat and meat food products distributed to [consumers] are wholesome, not adulterated, and properly marked, labeled, and packaged,” *id.* § 602; *see also Nat’l Meat Ass’n*, 565 U.S. at 456; *Kenney v. Glickman*, 96 F.3d 1118, 1120 (8th Cir. 1996). As explained, the FMIA does not mention worker safety. Accordingly, it is not within FSIS’s statutory mandate to issue regulations governing worker safety, nor are issues of workplace safety reasonably related to FSIS’s food safety mission. *Cf. Dawkins*, 226 F. Supp. 2d at 757 (“[T]he purpose and intent of the FSIS is to ensure food safety, not workplace safety.”). The agency recognized as much in

promulgating the NSIS rule. 84 Fed. Reg. at 52315. Instead, Congress has separately empowered OSHA with the statutory and regulatory authority to promulgate regulations regarding workplace health and safety. *See id; see generally* 29 U.S.C. § 651 *et seq.*

But the fact that FSIS ultimately concluded that it lacked enforcement authority over worker health and safety does not mean the agency failed to respond to (or to take into consideration) comments about worker safety in the final rule.⁶ Instead, FSIS acknowledged these comments and adequately explained its reasoning that under the FMIA, it “has neither the authority nor the expertise to regulate issues related to establishment worker safety.” *See* 84 Fed. Reg. 52315. It further explained that OSHA was the agency authorized to regulate with respect to such issues. *See id.*

And the agency went further still. FSIS concurred that “safe working conditions in swine slaughter establishments are important” and, although it properly explained that it could not take regulatory action to govern worker safety, the agency explained that it had supported and would continue to support OSHA’s efforts to promote workplace safety. *Id.* Specifically, FSIS pointed out in the rule that it has partnered with OSHA to implement several measures to assist the latter agency in fulfilling its mandate of assuring safe working conditions, while leaving to OSHA the ultimate decision as to whether to undertake regulatory or enforcement actions. *Id.* (“OSHA and FSIS will continue to partner through a Memorandum of Understanding to strengthen collaboration between FSIS inspectors and OSHA enforcement

⁶ Plaintiffs assert that, after soliciting comments on worker safety in the NPRM, FSIS reversed its position by claiming it “lacked authority” to consider harms to workers.” Compl. ¶¶ 62, 75–76. But the agency’s stance is that it lacks authority under the FMIA to regulate worker safety, not that it could never consider ways of supporting other agencies’ efforts to foster and promote worker safety. *See* 84 Fed. Reg. at 52315.

staff . . .").

Because FSIS did consider comments submitted regarding worker safety and was not authorized to regulate regarding issues with respect to which it lacks a statutory mandate, Counts One and Three should be dismissed as a matter of law.

D. As a Matter of Law, NSIS Complies with the FMIA's Requirement that FSIS Inspectors Inspect Each Carcass and Part.

Count Two of Plaintiffs' complaint likewise fails as a matter of law. Plaintiffs allege that the reduction in the number of online inspectors permitted under NSIS, combined with the elimination of maximum line speeds, results in a violation of the FMIA. *See* Compl. ¶¶ 78–80. The FMIA requires that FSIS inspectors conduct “a post mortem examination and inspection of the carcasses and parts thereof of all amenable species to be prepared at any slaughtering . . . or similar [U.S.] establishment . . . as articles of commerce which are capable of use as human food.” 21 U.S.C. § 604. Plaintiffs’ claim appears to turn on the allegation that, under NSIS, FSIS inspectors will not conduct a proper “inspection” within the meaning of the statute. *See* Compl. ¶¶ 78–80. But the D.C. Circuit considered and rejected the same argument in connection with the HIMP pilot over 17 years ago. *See generally AFGE II*, 284 F.3d 125. This Court should adopt the D.C. Circuit’s sound reasoning and follow suit, particularly given that FSIS has now implemented the relevant features of the program considered in *AFGE II* via notice-and-comment rulemaking.

Courts analyze an agency’s interpretation of its enabling statute under the *Chevron* framework. *See Rohr v. Reliance Bank*, 826 F.3d 1046, 1051 (8th Cir. 2016) (citing *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984)). Where a statute is unambiguous, courts look to its plain meaning to evaluate agency action. *See id.* But where the relevant

statutory language is ambiguous and Congress has empowered the agency to make rules carrying the force of law, courts afford “substantial deference” to the agency’s reasonable interpretation. *Friends of Boundary Waters Wilderness v. Bosworth*, 437 F.3d 815, 821 (8th Cir. 2006) (citing *United States v. Mead Corp.*, 533 U.S. 218, 230 (2001)). Agency interpretations afforded *Chevron* deference are given “controlling weight unless arbitrary, capricious, or manifestly contrary to the statute.” *Id.* (internal quotation marks and citation omitted).

Although the Eighth Circuit has not opined upon it, the D.C. Circuit has twice considered the meaning of the term “inspection” within § 604 of the FMIA. When first implementing the HIMP pilot, USDA proposed to fulfill this statutory requirement by having USDA inspectors observe establishment employees conducting carcass-by-carcass inspections. *See Am. Fed’n of Gov’t Emps., AFL-CIO v. Glickman*, 215 F.3d 7, 10 (D.C. Cir. 2000) (*AFGE I*). The D.C. Circuit rejected this approach, holding that observing establishment employees did not constitute an “inspection” because USDA inspectors were “inspecting people not carcasses.” *Id.* at 11. The FMIA requires “federal inspectors—rather than private employees—[to] make the critical determination whether a product is adulterated or unadulterated.” *Id.* *AFGE I* thus held that “[d]elegating the task of inspecting carcasses to plant employees violates the clear mandates of the FMIA.” *Id.*

In response to *AFGE I*, USDA modified the HIMP pilot to require that up to three online USDA inspectors examine each swine head, carcass, and viscera on the evisceration line. *See AFGE II*, 284 F.3d at 128. Plaintiffs challenged the modified program, and in *AFGE II*, the D.C. Circuit considered whether pre-inspection sorting by establishment employees, the reduction in the number of online USDA inspectors, and increased line speeds violated

the FMIA’s inspection requirement. *See id.* at 130. That court first noted that the term “inspection” was ambiguous, and because USDA did not act with the force of law when implementing the pilot program, it applied *Skidmore*, rather than *Chevron*, deference to USDA’s interpretation, taking into account the agency’s “body of experience and informed judgment.” *Id.* at 129 (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)). Observing that the FMIA does “not require organoleptic inspections” by federal inspectors, the D.C. Circuit found that the FMIA did not “prohibit[] establishment employees from paring down the overall number of carcasses by removing some adulterated carcasses before they get to FSIS inspectors.” *Id.* at 130. It also held that “higher line speeds [were] appropriate” under the program because “[f]ewer adulterated . . . hog parts and carcasses [would] be presented for federal inspection” as a result of establishment pre-sorting. *Id.* As such, the D.C. Circuit concluded that the program complied with the FMIA “because [it] calls for federal inspectors in participating hog plants to inspect all hog carcasses, heads and viscera, as the statute demands.” *Id.*

Here, NSIS incorporates the same key features as the modified HIMP pilot approved of in *AFGE II*. NSIS requires establishment personnel to sort carcasses and parts prior to FSIS inspection, and it permits establishments to set their own line speeds, provided they can maintain process control. 84 Fed. Reg. at 52300. Based on FSIS’s experiences under the HIMP pilot, the agency determined that pre-inspection sorting of carcasses resulted in federal inspectors being presented with healthier carcasses with fewer defects, permitting more efficient carcass-by-carcass inspections. *Id.* This, in turn, allows for FSIS to comply with the FMIA with fewer online federal inspectors and higher line speeds. *Id.* But FSIS made clear that, “[u]nder NSIS, FSIS inspectors will still be stationed on the evisceration line and these

inspectors will continue to inspect every head, viscera, and carcass.” *Id.* at 52311. And FSIS personnel have the authority to stop or slow the line if the speed interferes with FSIS inspectors’ ability to conduct carcass-by-carcass inspections. *Id.* at 52312. Thus, NSIS is entirely consistent with the FMIA’s requirement that “federal inspectors . . . inspect all hog carcasses, heads and viscera.” *AFGE II*, 284 F.3d at 130.

Nor does NSIS violate *AFGE I* by “[d]elegating the task of inspecting carcasses to plant employees.” 215 F.3d at 11. Although employees engage in pre-inspection sorting under NSIS, FSIS inspectors undertake an inspection of every carcass or part “which [is] capable of use as human food,” as the FMIA requires, 21 U.S.C. § 604, thus making “the critical determination whether a product is adulterated or unadulterated” prior to the product entering the market, *AFGE I*, 215 F.3d at 11; *see* 84 Fed. Reg. at 52311. That some carcasses, heads, or viscera may be trimmed or discarded by establishment employees prior to FSIS inspection does not alter the fact that an FSIS inspector examines each before it may be sold as a food product. *See AFGE II*, 284 F.3d at 130.

Moreover, unlike the HIMP pilot evaluated in *AFGE II*, NSIS is the product of notice-and-comment rulemaking, and the agency’s interpretation of “inspection” should thus be afforded *Chevron* deference—a higher level than that given in *AFGE II*. *See Mead Corp.*, 533 U.S. at 226–27; *AFGE II*, 284 F.3d at 129. Accordingly, FSIS’s determination that the procedures required under NSIS comport with the FMIA’s “inspection” requirement is controlling because it is based on both experience and reasonable conclusions, and is therefore neither “arbitrary, capricious, [n]or manifestly contrary to the statute.” *See Friends of Boundary Waters Wilderness*, 437 F.3d at 821 (citation omitted). Indeed, the *AFGE II* court recognized

that “experience with the program’s operation and effectiveness [would] doubtless play a significant role” in a final rulemaking undertaken by USDA. 284 F.3d at 130. It has here, confirming the agency’s predicted outcomes of the HIMP pilot. Thus, like that program, NSIS comports with the FMIA’s “inspection” requirement. *See id.*

CONCLUSION

For the foregoing reasons, Plaintiffs’ complaint should be dismissed.

Dated: December 6, 2019

Respectfully submitted,

JOSEPH H. HUNT
Assistant Attorney General

ERIC R. WOMACK
Assistant Director, Federal Programs Branch

/s/ Leslie Cooper Vigen
LESLIE COOPER VIGEN
Trial Attorney (D.C. Bar No. 1019782)
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W.
Washington, DC 20005
Tel: (202) 305-0727
Fax: (202) 616-8470
Email: Leslie.Vigen@usdoj.gov

Counsel for Defendant

CERTIFICATE OF SERVICE

I hereby certify that on December 6, 2019, I electronically filed the foregoing paper with the Clerk of Court using this Court's CM/ECF system, which will notify all counsel of record of such filing.

/s/ Leslie Cooper Vigen
LESLIE COOPER VIGEN
Trial Attorney (D.C. Bar No. 1019782)
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W.
Washington, DC 20005
Tel: (202) 305-0727
Fax: (202) 616-8470
Email: Leslie.Vigen@usdoj.gov